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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/042,407

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Satoshi Asai

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8994

20583

7590

04/29/2005

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EXAMINER

WILDER, CYNTHIA B

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/042,407

Applicant(s)

ASAI ET AL.

Examiner

Cynthia B. Wilder, Ph.D.

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13, 14, 16, 17 and 19-23 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 13, 14, 16, 17, and 19-23 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 22, 2005 has been entered. Claims 1-12, 15, and 18 have been canceled. Claims 13, 16, 17, 21, 22 and 23 have been amended. Claims 13-14, 16-17, 19-23 are pending and discussed below.

### ***Claim Rejections - 35 USC § 102(e)***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 13, 14, 16, 17 and 19-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Kingsman, Alan John (WO 01/62965 A2, filing date February 2001). Regarding claim 13, Kingsman teaches a method of screening to identify a gene whose function is unknown previously, as a target for drug development, which comprises (a) examining the expression of RNA or expression sequence tag(s) before and after an event using a high density microarray and making scattering plots showing changes in expression levels of the mRNAs or ESTs between,

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before and after the event, (b) determining those mRNA or ESTs whose expression has change in response to the event, from the results in the scattering plot and from databases searches for the mRNAs whose expression has changed in response to event, (c) designing a probe that will specifically hybridize with the mRNA and (d) performing hybridization of at least two types of tissues or cells of an organism before and after the event by using the one ore probes designed in step (c), (e) examining the localization of the mRNA in the tissues or cells before and after the event, (f) determining whether the localization of those mRNAs has changed in response to the event and (g) identifying those mRNAs whose expression and localization have both changed in response to the event as a target for drug development (page 10, lines 12-29; page 12, lines 13-27 to 15, lines 1-4; page 31, line 21 to page 32, line 30; See especially Examples 1 and 2 and Figure 2 which discloses scatter diagrams based on an event and the use of known genes to aid in the detecting the function of previously unknown and novel genes (see page 54 and table 1). Therefore, Kingsman meets the limitations of claim 13 of the instant invention.

Regarding claim 14, Kingsman teaches the method of claim 13, wherein the mRNA or EST is expressed in cultured cells or tissues (page 31, line 21 to page 32, line 16).

Regarding claim 16, Kingsman teaches the method of claim 13, wherein the gene encoding the mRNA and/or EST has been cloned (see example 2, especially pages 57, lines 1-5).

Regarding claim 17, Kingsman teaches the method of claim 13, wherein the localization of at least two different mRNA and/or expression sequence tags is determined in a single screening of the tissue or cell (Examples 1 and 2, especially page 47, lines 1-28).

Regarding claim 19, Kingsman teaches the method of claim 13, wherein the gene encodes a substance effective as a drug (Examples 1 and 2, especially page 39, lines 10-12 and page 42, lines 1-6).

Regarding claim 20, Kingsman teaches the method of claim 13, wherein the gene is related to a disease (See examples which disclose the association of the identified genes to cardiovascular disease, cancer, inflammatory disease, such as asthma (example 7), and cerebral ischemia (stroke). (See page 39, lines 10-12; page 62, line 23-26).

Regarding claim 21, Kingsman teaches the method of claim 13, further comprising determining the function of the gene (see Examples, especially example 6, page 62, line 23 to page 68, lines 1-3).

Regarding claim 22, Kingsman teaches the method of claim of claim 13, wherein the tissue or cell is collected from the organism at two or more different points in time after occurrence of an event (see example page 55, which discusses processing cells after incubating in normoxia and hypoxia conditions for 6 hours, with or without pretreatment for 16 hours with lipopolysaccharide; see also claim 26, page 79).

Regarding claim 23, Kingsman teaches the method according to claim 13 or 22, wherein the event is a condition, such as hypoxia that is associated with cancer or ischemia (See page 39, lines 10-12; page 62, line 23-26). Therefore, Kingsman also meets the limitations of claims 14, 16-17 and 19-23 of the instant invention.

#### ***Conclusion***

4. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose

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telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to [cynthia.wilder@uspto.gov](mailto:cynthia.wilder@uspto.gov). Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

  
CYNTHIA WILDER  
PATENT EXAMINER  
4/27/05